

EXPRESS MAIL NUMBER
EV 334 000 422 US

ANNULOPLASTY RINGS AND METHODS FOR REPAIRING CARDIAC VALVES

Field of the Invention

[0001] The invention relates to devices and methods for facilitating and simplifying the repair of cardiac valves.

Background of the Invention

[0002] The human heart has four valves which control the direction of blood flow in the circulation. The aortic and mitral valves are part of the “left” heart and control the flow of oxygen-rich blood from the lungs to the body, while the pulmonic and tricuspid valves are part of the “right” heart and control the flow of oxygen-depleted blood from the body to the lungs. The aortic and pulmonic valves lie between a pumping chamber (ventricle) and major artery, preventing blood from leaking back into the ventricle after it has been ejected into the circulation. The mitral and tricuspid valves lie between a receiving chamber (atrium) and a ventricle preventing blood from leaking back into the atrium during ejection.

[0003] Various disease processes can impair the proper functioning of one or more of these valves. These include degenerative processes (*e.g.*, Barlow’s Disease, fibroelastic deficiency), inflammatory processes (*e.g.*, Rheumatic Heart Disease) and infectious processes (*e.g.*, endocarditis). In addition, damage to the ventricle from prior heart attacks (*i.e.*, myocardial infarction secondary to coronary artery disease) or other heart diseases (*e.g.*, cardiomyopathy) can distort the valve’s geometry causing it to dysfunction.

[0004] Heart valves can malfunction in one of two ways. Valve stenosis is present when the valve does not open completely causing a relative obstruction to blood flow. Valve regurgitation is present when the valve does not close completely causing blood to leak back into the prior chamber. Both of these conditions increase the workload on the heart and are very serious conditions. If left untreated, they can lead to debilitating symptoms including congestive heart failure, permanent heart damage and ultimately death.

Dysfunction of the left-sided valves – the aortic and mitral valves – is typically more serious since the left ventricle is the primary pumping chamber of the heart.

[0005] Dysfunctional valves can either be repaired, with preservation of the patient's own valve, or replaced with some type of mechanical or biologic valve substitute. Since all valve prostheses have some disadvantages (*e.g.*, need for lifelong treatment with blood thinners, risk of clot formation and limited durability), valve repair, when possible, is usually preferable to replacement of the valve. Many dysfunctional valves, however, are diseased beyond the point of repair. In addition, valve repair is usually more technically demanding and only a minority of heart surgeons are capable of performing complex valve repairs. The appropriate treatment depends on the specific valve involved, the specific disease/dysfunction and the experience of the surgeon.

[0006] The aortic valve is more prone to stenosis, which typically results from buildup of calcified material on the valve leaflets and usually requires aortic valve replacement. Regurgitant aortic valves can sometimes be repaired but usually also need to be replaced. The pulmonic valve has a structure and function similar to that of the aortic valve. Dysfunction of the pulmonic valve, however, is much less common and is nearly always associated with complex congenital heart defects. Pulmonic valve replacement is occasionally performed in adults with longstanding congenital heart disease.

[0007] Mitral valve regurgitation is more common than mitral stenosis. Although mitral stenosis, which usually results from inflammation and fusion of the valve leaflets, can often be repaired by peeling the leaflets apart (*i.e.*, a commisurotomy), as with aortic stenosis, the valve is often heavily damaged and may require replacement. Mitral regurgitation, however, can nearly always be repaired but successful repair requires a thorough understanding of the anatomy and physiology of the valve, of the types of mitral valve dysfunction leading to mitral regurgitation and the specific diseases and lesions resulting in this dysfunction.

[0008] The normal mitral valve can be divided into three parts – an annulus, a pair of leaflets and a sub-valvular apparatus. The annulus is a dense ring of fibrous tissue which lies at the juncture between the left atrium and left ventricle. The annulus is normally elliptical or more precisely “kidney-shaped” with a vertical (anteroposterior) diameter approximately two-thirds of the horizontal diameter. The larger elliptical anterior leaflet and the smaller, crescent-shaped posterior leaflet attach to the annulus. Approximately

two-thirds of the annulus is attached to the posterior leaflet and one-third to the anterior leaflet. The edge of the leaflet which is not attached to the annulus is known as the free margin. When the valve is closed, the free margins of the two leaflets come together within the valve orifice forming an arc in the shape of a “smile” known as the line of coaptation. The corners of this “smile”, the two points on the annulus where the anterior and posterior leaflets meet (at approximately the 10 o’clock and 2 o’clock positions), are known as the commissures. The posterior leaflet is usually separated into three distinct scallops by small clefts which are referred to (from left to right) as P1, P2 and P3. The corresponding portions of the anterior leaflet directly opposite P1, P2 and P3 are referred to as A1, A2 and A3. The sub-valvular apparatus consists of two thumb-like muscular projections from the inner wall of the left ventricle known as papillary muscles and numerous chordae tendinae (or simply “chords”) which are thin fibrous bundles which emanate from the tips of the papillary muscles and attach to the free margin or undersurface of the valve leaflets in a parachute-like configuration.

[0009] The normal mitral valve opens when the left ventricle relaxes (diastole) allowing blood from the left atrium to fill the decompressed left ventricle. When the left ventricle contracts (systole), the increase in pressure within the ventricle causes the valve to close, preventing blood from leaking into the left atrium and assuring that all of the blood leaving the left ventricle (the stroke volume) is ejected through the aortic valve into the aorta and to the body. Proper function of the valve is dependent on a complex interplay between the annulus, leaflets and subvalvular apparatus.

[0010] Lesions in any of these components can cause the valve to dysfunction, leading to mitral regurgitation. Physiologically, mitral regurgitation results in increased cardiac work since the energy consumed to pump some of the stroke volume of blood back into the left atrium is wasted. It also leads to increased pressures in the left atrium which results in back up of fluid in the lungs and shortness of breath – a condition known as congestive heart failure.

[0011] Mitral valve dysfunction leading to mitral regurgitation can be classified into three types based on the motion of the leaflets (known as “Carpentier’s Functional Classification”). Type I dysfunction occurs despite normal leaflet motion. Lesions which can cause Type I dysfunction include a hole in the leaflet (usually from infection) or much more commonly distortion and dilatation of the annulus. Annular dilatation or

distortion results in separation of the free margins of the two leaflets. This gap prevents the leaflets from coapting allowing blood to regurgitate back into the left atrium during systolic contraction.

[0012] Type II dysfunction results from leaflet prolapse. This occurs when a portion of the free margin of one or both leaflets is not properly supported by the subvalvular apparatus. During systolic contraction, the free margins of the involved portions of the leaflets prolapse above the plane of the annulus into the left atrium. This prevents leaflet coaptation and allows blood to regurgitate into the left atrium between the leaflets. The most common lesions resulting in leaflet prolapse and Type II dysfunction include chordal elongation or rupture due to degenerative changes (such as myxomatous pathology or “Barlow’s Disease” and fibroelastic deficiency) or prior myocardial infarction.

[0013] Finally, Type III dysfunction results from restricted leaflet motion. Here, the free margins of portions of one or both leaflets are pulled below the plane of the annulus into the left ventricle. This prevents the leaflets from rising up to the plane of the annulus and coapting during systolic contraction. The restricted leaflet motion can be related to valvular or subvalvular pathology (usually fibrosis following damage from rheumatic heart disease) – referred to as Type IIIA dysfunction. It more commonly occurs when abnormal ventricular geometry or function leads to papillary muscle displacement which pulls the otherwise normal leaflets down into the ventricle, away from each preventing proper coaptation of the leaflets. This is known as Type IIIB dysfunction and usually results from prior myocardial infarction (“ischemia”) or severe ventricular dilatation and dysfunction (“cardiomyopathy”)

[0014] The anatomy and function of the tricuspid valve is similar to that of the mitral valve. It also has an annulus, chords and papillary muscles but has three leaflets (anterior, posterior and septal). The shape of the annulus is slightly different, more snail-shaped and slightly asymmetric. The demands on the tricuspid valve are significantly less than the mitral valve since the pressures in the right heart are normally only about 20% of the pressures in the left heart. Tricuspid stenosis is very rare in adults and usually results from very advanced rheumatic heart disease. Tricuspid regurgitation is much more common and can result from the same types of dysfunction (I, II, IIIA and IIIB) as the mitral valve. The vast majority of patients, however, have Type I

dysfunction with annular dilatation preventing leaflet coaptation. This is usually secondary to left heart disease (valvular or ventricular) which can, over time, lead to increased pressures back stream in the pulmonary arteries, right ventricle and right atrium. The increased pressures in the right heart can lead to dilatation of the chambers and concomitant tricuspid annular dilatation.

[0015] The benefits of valve repair over replacement are now well established in the cardiac surgical literature in all types of valve dysfunction and in nearly all disease states. Patients undergoing valve repair have been shown to live longer, with better preservation of cardiac function. The vast majority of patients with mitral or tricuspid regurgitation can have their valves successfully repaired instead of replaced. The likelihood of a successful repair, however, is highly dependent on the skill, knowledge and experience of the individual surgeon. Although most surgeons are comfortable performing simple valve repairs (annuloplasty rings, limited leaflet resections, etc.), many rarely perform valve repairs and only a small minority of surgeons are facile at more complex valve repairs. Most surgeons have inadequate knowledge and training in these techniques and, even if they had the technical ability, they do not encounter enough patients to feel comfortable with complex cases. This variability in surgical skill is reflected in the wide range of valve repair rates among different centers. High-volume, experienced centers routinely report valve repair rates over 90% while the national average is only 20-30%.

[0016] A typical mitral valve repair involves various procedures or stages, each one correcting a specific abnormality of a specific component of the valve apparatus. Specific techniques are available for each component (annulus, leaflet segments, chords, and papillary muscles) of the valve. The annular circumference and shape can be restored with an annuloplasty device (ring or band) which is attached to the annulus using sutures. Annular calcification can be excised. Excess or prolapsing leaflet tissue can be resected and reconstructed. Shrunken or restricted leaflet segments can be augmented with a patch of autologous tissue. Leaflet segments can be partially detached from the annulus and advanced to cover a gap from a leaflet resection (known as a sliding valvuloplasty). Ruptured or elongated chords can be replaced with artificial chords or by transferring redundant chords from another leaflet segment. Shrunken or

fused chords can be released or split. Occasionally, the papillary muscles themselves can be shortened to correct prolapse from multiple elongated chords.

[0017] The power of Carpentier's functional classification system is that the appropriate surgical techniques derive directly from the type of dysfunction. Patients with Type I valve dysfunction (normal leaflet motion due to annular dilatation) and Type IIIB valve dysfunction (restricted leaflet motion due to ventricular distortion) can usually be repaired with implantation of an annuloplasty ring alone. In Type I valve dysfunction, the annuloplasty is sized based on the dimensions of the anterior leaflet to restore the annulus to its original size. In Type IIIB valve dysfunction, the annuloplasty must be downsized to account for restricted leaflet motion.

[0018] Patients with Type II and IIIA valve dysfunction usually require more complex repairs. Type IIIA valve dysfunction (restricted leaflet motion due to valvular/subvalvular pathology) can require leaflet augmentation and/or chordal release/splitting. Type II valve dysfunction (leaflet prolapse) usually requires some type of leaflet resection and reconstruction along with, on occasion, additional leaflet and chordal procedures. The most common type of valve repair for Type II valve dysfunction is a quadrangular resection of the middle (P2) segment of the posterior leaflet with advancement and approximation of the remaining (P1 and P3) segments (a sliding valvuloplasty). Many surgeons are comfortable repairing straightforward cases of P2 prolapse. More complex Type II cases, including those with anterior leaflet involvement or prolapse at or near the commissures, usually require additional procedures such as chordal transfer, placement of artificial chords or additional leaflet resections. Most surgeons, outside of specialized centers, rarely tackle these complex repairs and these patients usually receive a valve replacement. New devices or techniques which simplify complex Type II repairs would greatly expand the proportion of patients who benefit from valve repair over replacement.

[0019] Nearly all experienced valve repair surgeons agree that all patients undergoing mitral valve repair must have an annuloplasty procedure performed to assure a successful, durable repair. The annuloplasty serves two main purposes. It restores the shape and size of the annulus to permit adequate leaflet coaptation and prevent regurgitation. It also serves to stabilize any additional repair work by taking tension off of any suture lines. Although annuloplasties were originally performed using a suture

woven in and out of the annulus like a purse string, nearly all surgeons today utilize a prosthetic annuloplasty device. This is usually a prosthetic ring or band that is attached within the heart to the dilated and distorted annulus using multiple sutures. The annuloplasty usually includes an inner frame made of metal, such as stainless steel or titanium, or of a flexible material, such as silicone rubber or Dacron cordage, and is covered with a biocompatible fabric or cloth into which the sutures are placed. The rings may be rigid, semi-rigid or flexible, and they may form a complete continuous ring, a split ring or a partial ring or band. Annuloplasty rings may be provided in one of several shapes – circular, D- or “kidney” shaped or C-shaped. Rings are usually specifically designed for the mitral or tricuspid valves. An annuloplasty ring system usually consists of rings of various sizes (24 to 40 mm) loaded on specialized holders to facilitate placement along with a series of sizers to measure the dimensions of the patient’s valve.

[0020] Common examples of rigid annuloplasty rings are the original Carpentier ring disclosed in U.S. Patent No. 3,656,185, the more current Carpentier-Edwards® ring (distributed by Edwards Laboratories) disclosed in U.S. Patent No. 5,061,277, and the ring disclosed in U.S. Patent No. 4,164,046, which are hereby incorporated by reference. Examples of semi-rigid annuloplasty rings include the Carpentier-Edwards Physio™ ring as disclosed in U.S. Patent No. 5,104, 407 and the ring disclosed in U.S. Patent No. 4,489,446, which are hereby incorporated by reference. Common examples of flexible rings include the Duran ring (distributed by Medtronic) as disclosed in Duran et al., Circulation (Suppl. I) 78:91-96(1989) and the Puig-Massana ring as disclosed in U.S. Patent No. 4,290,151, which are hereby incorporated by reference. Other annuloplasty rings include the Seguin Ring (made by St. Jude), the Carbomedics rings, the Colvin-Galloway Ring (made by Medtronic), the Carpentier Tricuspid Ring and the Edwards MC3 Tricuspid Ring.

[0021] Each of these types of annuloplasty rings has advantages and disadvantages that are commonly understood in the field of mitral valve repair. Rigid and semi-rigid rings are believed to more completely restore the shape as well as the circumference of the annulus. As such they are said to perform a “remodeling” (shape restoring) annuloplasty in addition to a “reduction” (circumference decreasing) annuloplasty. It has been shown experimentally that restoring and fixing the vertical (anteroposterior) dimension of the

annulus is critical to restoring leaflet coaptation and thus to a successful annuloplasty procedure. Rigid and semi-rigid rings more reliably fix this dimension than flexible rings. Flexible rings, however, are somewhat easier to insert and secure to the annulus which might decrease the (albeit low) incidence of post-operative ring detachment (“dehiscence”). They are also purported to preserve the normal three dimensional “saddle” shape of the annulus and its complex motion during the cardiac cycle. Complete rings (rigid or flexible) have the advantage of fixating the entire annulus which should decrease the incidence of late failures due to progressive dilatation of the annulus. Partial rings (more precisely bands) are designed to reduce and fixate the posterior annulus only and are based on the fact that the anterior third of the annulus is part of the fibrous skeleton of the heart and should be less prone to dilate. The advantage of a partial band is that it requires less sutures to secure and eliminates the anterior annular sutures which are typically the most difficult to visualize and place.

[0022] Since they involve work inside the heart chambers, conventional procedures for replacing or repairing cardiac valves require the use of the heart-lung machine (cardiopulmonary bypass) and stopping the heart by clamping the ascending aorta and perfusing it with high-potassium solution (cardioplegic arrest). Although most patients tolerate limited periods of cardiopulmonary bypass and cardiac arrest well, these maneuvers are known to adversely affect all organ systems. The most common complications of cardiopulmonary bypass and cardiac arrest are stroke, myocardial “stunning” or damage, respiratory failure, kidney failure, bleeding and generalized inflammation. If severe, these complications can lead to permanent disability or death. The risk of these complications is directly related to the amount of time the patient is on the heart-lung machine (“pump time”) and the amount of time the heart is stopped (“crossclamp time”). Although the safe windows for pump time and cross clamp time depend on individual patient characteristics (age, cardiac reserve, comorbid conditions, etc.), pump times over 4 hours and clamp times over 3 hours can be concerning even in young, relatively healthy patients. Complex valve repairs can push these time limits even in the most experienced hands. Even if he or she is fairly well versed in the principles of mitral valve repair, a less experienced surgeon is often reluctant to spend 3 hours trying to repair a valve since, if the repair is unsuccessful, he or she will have to spend up to an additional hour replacing the valve. Thus, time is a major factor in

detering surgeons from offering the benefits of valve repair over replacement to more patients. Devices and techniques which simplify and expedite valve repair would go a long way to eliminating this deterrent.

[0023] Within recent years, there has been a movement to perform many cardiac surgical procedures “minimally invasively” using smaller incisions and innovative cardiopulmonary bypass protocols. The purported benefits of these approaches include less pain, less trauma and more rapid recovery. This has included “off-pump coronary artery bypass” (OPCAB) surgery which is performed on a beating heart with the use of cardiopulmonary bypass and “minimally invasive direct coronary artery bypass” (MIDCAB) which is performed through a small thoracotomy incision. A variety of minimally invasive valve repair procedures have been developed whereby the procedure is performed through a small incision with or without videoscopic assistance and, more recently, robotic assistance. However the use of these minimally invasive procedures has been limited to a handful of surgeons at specialized centers. Even in their hands, the most complex valve repairs cannot be performed since dexterity is limited and the whole procedure moves more slowly. Devices and techniques which simplify valve repair have the potential to greatly increase the use of minimally invasive techniques which would significantly benefit patients.

[0024] Thus, it is desirable to provide a single device which, when operatively used, only requires a simplified procedure by which to repair a cardiac valve, and a mitral valve in particular. For example, it would be beneficial to provide a device which, when properly implanted, not only remodels the defective valve annulus but also corrects other problems, such as leaflet prolapse, thereby obviating the need to perform ancillary procedures to correct leaflet size and shape, to reattach or shorten chordae, etc. With such a device, most patients with Type II valve dysfunction could be corrected by device implantation alone or with a limited P2 leaflet resection. Many patients with Type IIIA valve dysfunction could be corrected with aggressive leaflet mobilization (chordal cutting) followed by device implantation. Simplifying the repair procedure would decrease the amount of time the patient’s heart would need to be stopped and bypassed with a heart-lung machine and increase the likelihood that it could be performed minimally invasively. This would not only decrease the potential for complications, it would also allow a broader group of surgeons to perform the procedure.

Relevant Literature

- [0025] 1. Mohty D, Orszulak TA, Schaff HV, Avierinos JF, Tajik JA, Enriquez-Sarano M. Very Long-Term Survival and Durability of Mitral Valve. *Circulation* 2001;104[suppl I]:I-1-I-7.
2. Chauvaud, S.; Fuzellier, J. F.; Berrebi, A.; Deloche, A.; Fabiani, J. N., and Carpentier, A. Long-term (29 years) results of reconstructive surgery in rheumatic mitral valve insufficiency. *Circulation* 2001; 104(12 Suppl 1):I12-5.
3. Braunberger, E.; Deloche, A.; Berrebi, A.; Abdallah, F.; Celestin, J. A.; Meimoun, P.; Chatellier, G.; Chauvaud, S.; Fabiani, J. N., and Carpentier, A. Very long-term results (more than 20 years) of valve repair with Carpentier's techniques in nonrheumatic mitral valve insufficiency. *Circulation*. 2001; 104(12 Suppl 1):I8-11.
4. Carpentier, A. F.; Lessana, A.; Relland, J. Y.; Belli, E.; Mihaileanu, S.; Berrebi, A. J.; Palsky, E., and Loulmet, D. F. The "physio-ring": an advanced concept in mitral valve annuloplasty. *Ann Thorac Surg*. 1995 Nov; 60(5):1177-85.
5. Carpentier, A. Cardiac valve surgery--the "French correction". *J Thorac Cardiovasc Surg*. 1983 Sep; 86(3):323-37.
6. Aklog, L.; Adams, D. H.; Couper, G. S.; Gobezie, R.; Sears, S., and Cohn, L. H. Techniques and results of direct-access minimally invasive mitral valve surgery: a paradigm for the future. *J Thorac Cardiovasc Surg*. 1998 Nov; 116(5):705-15.
7. Savage EB, Ferguson TB, DiSesa VJ. Use of Mitral Valve Repair: Analysis of Contemporary United States Experience Reported to the Society of Thoracic Surgeons National Cardiac Database. *Ann Thorac Surg* 2003;75:820 –5.

Summary of the Invention

- [0026] The present invention includes annuloplasty devices and methods of using the subject devices to repair cardiac valves. Kits including at least one of the subject devices are also provided. The present invention is particularly suitable for repairing regurgitant mitral valves secondary to Type II valve dysfunction (leaflet prolapse) although has potential for use in all types of mitral or tricuspid valve dysfunction.
- [0027] An object of the present invention is to simplify the mitral valve repair procedures and obviate the need to perform anything other than an annuloplasty

procedure, *i.e.*, implantation of the annuloplasty ring, to completely correct a defective cardiac valve regardless of the number and types of particular defects inflicting the valve. Another object of the invention is to employ a single device and a single procedure to completely correct valve dysfunction. In certain circumstances where the device might not completely eliminate the need for adjunctive procedures, the number and complexity of these procedures and the time and expertise necessary to perform them would be significantly reduced.

[0028] As is known from the use of conventional annuloplasty rings, even a properly sized and implanted ring, while adequately correcting the shape and size of the valve's annulus to fully correct mitral regurgitation when leaflet motion is normal (Type I valve dysfunction), does not necessarily bring the valve to full proper functioning when leaflet prolapse (Type II valve dysfunction) or severe leaflet restriction (Type III valve dysfunction) is present. Ancillary procedures, including leaflet resection, chordal transfer and reattachment are usually required for leaflet prolapse and leaflet augmentation or chordal resection may be required for restricted leaflet motion.

[0029] A feature of the present invention is the provision of an implantable device having an annuloplasty ring and a restraining or support structure or mechanism for restraining the abnormal motion of at least a portion of one or more of the valve leaflets. The annuloplasty ring functions to correct the shape and size of the annulus bringing the leaflets in proximity to permit coaptation. The restraint mechanism functions to ensure proper coaptation of the leaflets, regardless of the number, type and anatomical location of the valvular defects, without the need for procedures other than proper implantation of the ring in most cases. As a result, specific chordal or leaflet procedures may not need to be performed as their collective ill-effects can be resolved solely by implantation of the subject device. In some cases, the surgeon may choose to perform relatively straightforward ancillary procedures such as a limited posterior leaflet resection or mobilization while allowing the restraint mechanism to correct any new or residual prolapse.

[0030] The restraining structure consists of one or more restraining members extending inside the orifice of the ring. The restraining member or members may have a variety of different shapes and configurations including, but not limited to, chord-shaped or ribbon-shaped, rigid, semi-rigid or flexible, straight or bowed, elastic or inelastic or solid. They

can attach to the ring or to another member, forming any pattern, creating a net-like or rigid structure which prevents prolapse of the leaflet or leaflets. By restraining the prolapsing segment or by providing a new intra-annular coaptation plane, the restraint system facilitates coaptation of the leaflets(s) thereby eliminating the regurgitation. Thus, the restraining structure of the device corrects Type II valve dysfunction (leaflet prolapse) without the need for the usual additional ancillary procedures to correct leaflet prolapse such as leaflet resection, transfer or artificial chordal attachment.

Brief Descriptions of the Drawings

- [0031] Fig. 1A is a top view of a mitral valve having a dilated and deformed annulus (circular rather than elliptical) resulting in poor coaptation of the anterior and posterior leaflets with a visible gap between therebetween.
- [0032] Fig. 1B is a cross-sectional view of the left side of the heart illustrating the left atrium, the left ventricle, the dysfunctional mitral valve of Fig. 1A, the aortic valve and the ascending aorta. The anterior leaflet of the mitral valve is shown prolapsing into the left atrium above the plane of the annulus as a result of an elongated chord. This prevents it from coapting against the posterior leaflet thereby creating a gap which results in regurgitation of blood into the left atrium during systolic contraction.
- [0033] Fig. 2A is a view from the left atrium of one embodiment of a D-shaped annuloplasty device of the present invention, shown operatively attached to the annulus of the mitral valve of Fig. 1A, having a restraining structure including a primary, horizontal restraint and secondary restraints crossing between it and the posterior portion of the device body across the line of coaptation of the valve leaflets.
- [0034] Fig. 2B is a cross-sectional view of the left side of the heart having the annuloplasty device of Fig. 2A operatively implanted (shown along line b-b) within and correcting the defective mitral valve within the heart of Fig. 1B. The restraining structure corrects the defective mitral valve by preventing the anterior leaflet of the valve from prolapsing into the left atrium above the plane of the annulus, allowing it to coapt against the posterior leaflet of the valve.
- [0035] Figs. 3A-D illustrate four other exemplary embodiments of the annuloplasty device of the present invention having a D-shaped configuration, wherein the device of Fig. 3A has zigzagging secondary restraints extending between a primary horizontal

restraint and the posterior segment of the ring; the device of Fig. 3B has intersecting secondary restraints extending between a primary, horizontal restraint and the posterior segment of the ring; the device of Fig. 3C has intersecting restraints extending between the anterior and posterior segments of the ring without a primary restraint; and the device of Fig. 3D has parallel restraints extending between the anterior and posterior segments of the ring without a primary restraint.

[0036] Figs. 4A-D illustrate four exemplary embodiments of the annuloplasty devices of the present invention having a circular ring, wherein the device of Fig. 4A has substantially parallel transverse restraints extending between the anterior and posterior segments of the ring; the device of Fig. 4B has zigzagging restraints extending between the anterior and posterior segments of the ring; the device of Fig. 4C has substantially parallel or slightly angular secondary restraints extending between a primary cross-restraint and the posterior segment of the ring; and the device of Fig. 4D has a smaller, inner ring substantially concentric within the outer annuloplasty ring and intersecting restraints extending between the inner and outer rings.

[0037] Figs. 5A-D illustrate four exemplary embodiments of the annuloplasty device of the present invention having a C-shape, wherein the device of Fig. 5A has substantially parallel restraints extending between a cross-bar and the posterior segment of the ring; the device of Fig. 5B has zigzagging restraints extending between a cross-bar and the posterior segment of the ring; the device of Fig. 5C has intersecting restraints extending between a cross-bar and the posterior segment of the ring; and the device of 5D has intersecting restraints extending between the ring.

[0038] Figs. 6A and 6B illustrate two exemplary embodiments of the annuloplasty device of the present invention having an open saddle shape, wherein Fig. 6A has substantially parallel restraints extending between a cross-bar and the posterior segment of the ring; and Fig. 6B has intersecting restraints extending between a primary restraint and the posterior segment of the ring.

Detailed Description of the Invention

[0039] The present invention includes implantable prosthetic devices and methods of using the subject devices to repair cardiac valves. The prosthetic devices include annuloplasty rings which, when operatively employed, are sutured into the annulus of a

defective or deformed valve, thereby correcting the defect or deformation and rendering the valve competent. Kits including at least one of the subject devices are also provided. The present invention is particularly suitable for repairing the mitral valve and, thus, is described in the context of mitral valve repair for purposes of example only. However, the present invention is also suitable for the repair of tricuspid valves and other valves.

[0040] Before the present invention is described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0041] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

[0042] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[0043] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

DEFINITIONS

- [0044] The terms “annuloplasty ring” and “ring” are used interchangeably herein when referring to the annular member of the annuloplasty devices of the present invention and are meant to encompass any configuration or shape of annuloplasty ring including, but not limited to, configurations which are split (*i.e.*, have an open circumference) or continuous (*i.e.*, have a closed circumference), including, but not limited to, flexible, semi-rigid and rigid devices and including, but not limited to, shapes which are circular, D-shaped, C-shaped, saddle shaped and any other annular or non-annular shape suitable for repairing cardiac valves, whether or not specifically described herein.
- [0045] The term “annuloplasty device” as used herein includes the annuloplasty ring of the present invention in addition to any and all other components, *e.g.*, the restraining structure, integral with the ring.
- [0046] The terms “major axis” and “longitudinal axis” are used interchangeably herein when referring to the axis defined generally along the direction of a greater diameter of those annuloplasty rings of the present invention having other than a circular shape.
- [0047] The terms “minor axis” and “transverse axis” are used interchangeably herein when referring to the axis defined generally along the direction transverse to the major axis of those annuloplasty rings of the present invention having other than a circular shape.
- [0048] The term “horizontal axis” is used herein when referring to the axis which bisects, generally in the horizontal direction according to the views depicted in the relevant Figures herein, those annuloplasty rings of the present invention having a circular shape.
- [0049] The term “vertical axis” is used herein when referring to the axis which bisects, generally in the vertical direction according to the views depicted in the relevant Figures herein, those annuloplasty rings of the present invention having a circular shape.

THE ANNULOPLASTY DEVICES

- [0050] Referring to the drawings, wherein like reference numbers refer to like components throughout the drawings, Fig. 1A illustrates a top view, *i.e.*, 10 as viewed from the left atrium, of a regurgitant mitral valve having an annulus 2, anterior leaflet 4 and posterior leaflet 6. Mitral valve 10 suffers from poor coaptation of the leaflets as

evidenced by gap 8 between them. In addition, the annulus 2 is dilated and deformed, taking on a circular instead of a kidney shape. Fig. 1B is a cross-sectional view of the left side of a heart having a left ventricle 14, a left atrium 16 and mitral valve 10 situated at the atrioventricular passageway there between. The anterior leaflet 4 and posterior leaflet 6 are connected to the papillary muscles 18 by chordae tendinae 12. Mitral valve 10 has Type II valve dysfunction with prolapse of the free margin of the anterior leaflet 4 above the plane of the annulus 2 as a result of elongation of the chordae 12 to this leaflet. This prolapse prevents the anterior leaflet 4 from coapting with posterior leaflet 6 resulting in a gap 8 through which blood regurgitates from the left ventricle 14 into the left atrium 16 during systolic contraction. Fig. 1B further illustrates the effect that the dilation of the annulus 10 has on incomplete coaptation. The various embodiments of the annuloplasty devices of the present invention, which will now be described in detail, function to correct the defective mitral valve 10 when properly implanted therein.

[0051] Figs. 2A and B illustrate one embodiment of an annuloplasty device 20 of the present invention. Device 20 includes a complete D-Shaped semi-rigid ring 21 operatively implanted into the defective mitral valve 10 by means of a plurality of interrupted mattress sutures 28 which are sewn through ring 21 and into the annulus (not visible due to obstruction by ring 21). Other means known in the art for attaching annuloplasty rings may also be used with those of the present invention including, but not limited to, a continuous running suture, interrupted simple (non-mattress) sutures, specialized clips or staples. The commissural marks 26a and 26b are guides to identify the approximate location of the valve commissures and separate the ring into an anterior segment 22 and posterior segment 24.

[0052] Extending across a portion of the interior area of the ring 21 is a net-like restraining structure 30. Restraining structure 30 can include any number of restraining members in any pattern as long as they create a net which covers any prolapsing segments of either leaflet. The number of restraining members, the gaps between them and their pattern can be optimized to maximize the ability of the restraining structure to restrain prolapsing tissue, while minimizing the amount of prosthetic material in contact with leaflet tissue and avoiding any turbulence and obstruction to flow. In this particular embodiment, a primary cross-bar restraint 32 extends across the major axis of ring 21. More specifically, cross-restraint 32 spans ring 21 between commissural junctures 26a

and 26b; however, cross restraint 32 may extend between and attach to ring 21 at any appropriately corresponding locations on either side of junctures 26a and 26b. For example, cross restraint 32 may extend between corresponding locations 27a and 27b, or between corresponding locations 29a and 29b. Secondary restraining members 34 extend generally along the minor axis from the posterior ring segment 24 over the line of coaptation 8 to the primary cross-bar restraint 32.

[0053] As can be seen in Figs. 2A and 2B, when operatively implanted into the regurgitant mitral valve 10, anterior segment 22 of ring 21 is attached to the anterior portion of mitral valve annulus 2, which abuts and is supported by the base of aorta 25. Posterior segment 24 of ring 21 is attached to the posterior portion of annulus 2. As such, annuloplasty ring 21 functions to remodel valve annulus 2 to its proper shape and size, thereby bringing leaflets 4 and 6 into proximity. In patients with Type I valve dysfunction (pure annular dilatation with normal leaflet motion) this annular remodeling and re-approximation of the two leaflets 4 and 6 would suffice to permit adequate coaptation of the leaflets. In patients with Type II valve dysfunction (leaflet prolapse), one or more leaflet segments are not supported by the subvalvular apparatus as a result of chordal elongation or rupture. In the illustrated example (Fig 1B), the anterior leaflet 4 prolapses into the left atrium as a result of elongation of the chordae 12. Thus, bringing the leaflets in proximity to each other is not adequate to assure proper leaflet coaptation since the prolapsing anterior leaflet 4 is displaced into the left atrium 16 during systolic contraction maintaining the gap 8 through which blood can still regurgitate. Conventional valve repair would require adjunctive procedures to the prolapsing anterior leaflet 4 or the elongated chord 12 to correct the prolapse. With insertion of the annuloplasty device 20, however, the restraining structure 30 prevents the prolapsing anterior leaflet 4 from being displaced into the left atrium. By keeping this segment under the plane of the annulus 2, the restraining structure 30 allows the previously prolapsing anterior leaflet 4 to coapt against the non-prolapsing posterior leaflet 6 which has been brought into proximity to anterior leaflet 4 by the remodeling effect of the annuloplasty ring 21.

[0054] To understand the ability of the restraining structure 30 to correct regurgitation resulting from Type II valve dysfunction and various design considerations for the structure 30, it is important to emphasize the precise definition of leaflet prolapse and

contrast it to leaflet billowing. With leaflet prolapse the free margin or edge of the leaflet (where the chordae are attached) is displaced into the left atrium 16 during systolic contraction preventing leaflet coaptation and results in regurgitation. With leaflet billowing, on the other hand, the body of the leaflet balloons into the left atrium above the plane of the annulus but the free margin remains below the plane of the annulus. The coapting portion of the leaflet near the free margin remains below the plane of the annulus; it is able to coapt with the other leaflet as long as they are in proximity and not separated as a result of annular dilatation. Leaflet billowing is abnormal, may result in increased stress on the attached chordae and is thought to be a precursor to prolapse and regurgitation. It may also contribute to late failures after mitral valve repair as a result of increased chordal stress. Leaflet billowing, however, does not cause mitral regurgitation unless it is associated with leaflet prolapse.

[0055] In order to correct leaflet prolapse, the net-like restraining structure 30, at a minimum, preferably covers the entire posterior leaflet 6, the gap 8 between the leaflets and the coapting portion of the anterior leaflet 4 (the portion which would normally make contact with the posterior leaflet 4) such as that illustrated in Fig 2A. As such, cross-restraint 32 is positioned at least a requisite distance from posterior segment 24 of ring 21. Exemplary end-to-end fixation locations for cross-restraint 32 are identified on ring 21 at 26a and 26b or, alternatively, at 27a and 27b or at 29a and 29b. The greater this distance, the greater the length of the restraining members 34. While sufficient coverage of the posterior leaflet 6 is necessary, the increased length in the restraining members increases the amount of prosthetic material in contact with the leaflet tissue which may result in increased turbulence and obstruction of blood flow. Thus, a primary advantage of minimizing the surface area of the net-like restraining structure 30 is decreasing the amount of prosthetic material in contact with leaflet tissue and thereby decreasing the amount of turbulence and obstruction to blood flow. However, there may be several potential disadvantages with such a minimal configuration. First, if the posterior leaflet is large and an adjunctive posterior leaflet resection is not performed, the line of coaptation 8 could lie significantly more anterior than is shown in Fig 2A. If this occurred the net-like restraining structure might not fully cover the line of coaptation 8 which would allow a prolapsing segment of the anterior leaflet 4 to protrude through the device and cause regurgitation. A similar situation may occur where there is

significant billowing of the anterior leaflet 4. If the billowing segment protrudes anterior to the cross restraint (*i.e.*, outside of the net), it could, if severe, drag a prolapsing segment with it preventing coaptation and causing regurgitation. Finally, even if billowing of the anterior leaflet does not result in prolapse, it could nonetheless put additional stress on the chords which might impact the long term durability of the repaired valve. Therefore, it might be desirable to restrain the billowing portion as well as the prolapsing portion of the anterior leaflet which might require a larger restraining structure 30 with the cross-restraint positioned closer to the anterior annulus 22 or, perhaps, extending the restraining members across the entire diameter of the ring (eliminating the need for a cross-restraint), such as provided in the embodiments of Figs. 3C and 3D.

[0056] The design considerations for the secondary restraining members 34 are similar. The number of restraint members 34 is preferably kept to a minimum to minimize the amount of prosthetic material and the consequences thereof. The force generated by the prolapsing leaflet segment as it abuts the restraining structure 30 will be distributed across the restraint member with which it is in contact. Therefore, increasing the number of restraining members would decrease the stress on each individual member allowing it to be constructed from a finer gauge material. However, if there are too few restraining members, the gap between them might be wide enough to allow a prolapsing segment of either leaflet to slip through the gap unrestrained. The standard teaching in mitral valve repair is that the free margin of a leaflet must be supported by a good quality chord 12 (*i.e.*, one that is not elongated or too thin) at least every 5-7 millimeters along the leaflet. Using this guideline, device 20 should have secondary restraint members 34 spaced at a similar interval or slightly wider. It is also possible that the optimal configuration would have these members spaced unevenly to accommodate greater prolapsing forces centrally than near the commissures.

[0057] Figs. 3A-D illustrate a few other exemplary embodiments of a D-shaped annuloplasty device of the present invention, each including a ring 52 having anterior segment 54 and posterior segment 56 with their respective circumferential lengths are determined by the location of junctures 64a, 64b. Device 50 of Fig. 3A has restraining structure 58 which has a configuration generally similar to that of restraining structure 30 of annuloplasty device 20 of Fig. 2A, and defined by primary cross-restraint 60 and

secondary restraints 62. Primary cross-restraint 60 has a configuration and is positioned similar to that of cross-restraint 32 of Fig. 2A; however, secondary restraints 62, of which there are twelve, have a running zigzag pattern between cross-restraint 60 and posterior segment 56. Also, the thickness of cross-restraint 60 is substantially greater than that of secondary restraints 62.

[0058] Annuloplasty device 70 of Fig. 3B has cross-restraint 80 having a configuration the same as annuloplasty device 50 of Fig. 3A; however, secondary restraints 82 have a criss-crossing pattern or form a series of “Xs”. Each leg or secondary restraint 82 of each X may extend between and have its ends attached to cross-restraint 80 and posterior segment 56 of ring 52. Alternatively, as illustrated in Fig. 4B, the criss-crossing pattern may be formed by a plurality of restraint members, each wrapped a single time around cross-restraint 80 and having their respective ends affixed to posterior segment 56. The attachment points of the respective strands are staggered such that the resulting criss-crossing pattern of restraining structure 78 is formed. Similar to the device of Fig. 2A, primary cross-restraint 80 is thicker than secondary restraints 82.

[0059] Fig. 3C and 3D illustrate annuloplasty devices 90 and 110 with restraining structures 98 and 118 which, unlike the previously described annuloplasty devices of the present invention, do not include a cross-restraint member and thus covers the entire ring orifice with transverse restraints extending from the anterior segment 54 to the posterior segment 56 of the ring. In Fig. 3C, the transverse restraining members 100 are substantially transverse to the major axis of ring 52 and are configured in a criss-crossing pattern wherein each of the legs of the Xs is attached to ring 52. Fig. 3D illustrates another D-shaped annuloplasty device 110 having a restraining structure 118 having only transverse restraints 120. Transverse restraints 120 are parallel to each other and extend between and are attached to anterior segment 54 and posterior segment 56 of ring 52.

[0060] Figs. 4A-D illustrate annuloplasty devices having a circular ring 124 configuration. Circular rings tend to be completely flexible and reduce the circumference of the annulus without remodeling it to a specific shape. Surgeons who use circular rings value the precise, measured reduction of the annular circumference but feel that ring flexibility is important to maintain the normal dynamic geometry of the annulus and to minimize the risk of ring dehiscence (late detachment secondary to poor

healing of the ring to the annulus). Each of the rings 124 have an anterior segment 126 and a posterior segment 128 attached to each other at junctures 130a, 130b. Anterior segment 126 extends over approximately 1/3 of ring 124 and the remaining approximate 2/3 of ring 124 comprise posterior segment 128. The restraining structures of each of these annuloplasty devices 122 have varying configurations that will now be discussed individually.

[0061] The restraining structure 132 of annuloplasty device 131 of Fig. 4A includes five (but may include more or less) varying-length restraints 134 along the vertical axis, wherein the three central restraints 134 extend between anterior segment 126 and posterior segment 128 of ring 124, and the two outer restraints each extend between respective points on posterior segment 128 only. As with all embodiments of the present invention, any suitable number and ring attachment locations of restraints 134 may be employed. Restraints 134 do not intersect each other within the interior of ring 124 and are not quite parallel to each other. Instead, restraints 134 extend somewhat radially from the center section of posterior segment 128 to either the anterior segment 126 or the distal portion of posterior segments 128.

[0062] The restraining structure 136 of annuloplasty device 135 of Fig. 4B also provides restraints 138 which extend between sides of ring 124 generally along the vertical axis but in a zigzag configuration. Here, ten restraints 138 are employed, but more or less may be used.

[0063] The restraining structure 140 of annuloplasty device 139 of Fig. 4C includes both a cross-restraint 142 generally along the horizontal axis and secondary restraints 144 situated generally along the vertical having a configuration and pattern similar to that of restraining structure 30 of annuloplasty device 20 of Fig. 2A. Here, again, primary restraint 142 is thicker than secondary restraints 144 but could also be of the same thickness material as the secondary restraints.

[0064] Fig. 4D illustrates an annuloplasty device 145 having a restraining structure 146 which is significantly different from the previously discussed restraining structures of the present invention. In particular, restraining structure 146 includes a primary or annular restraint 146 disposed concentrically within ring 124. While annular restraint 146 is positioned centrally in this embodiment, the annular restraint may be positioned at any suitable location within the interior of ring 124. A plurality of secondary or

transverse restraints 150 extends across the area between annular restraint 146 and ring 124. Here, the various restraints form a star-like pattern and are each attached to the perimeter of annular restraint 146 as well as to ring 124 at two corresponding locations. Again, secondary restraints 150 are thinner than primary restraint 146. The inner ring provides an unobstructed central orifice for flow.

[0065] Figs. 5A-D illustrate annuloplasty devices having an open ring configuration 152, and specifically a flexible C-shaped configuration wherein ring 152 is comprised only of a posterior segment. Surgeons who utilize flexible partial rings (bands) feel that the annular dilatation that occurs with mitral regurgitation is limited to the posterior portion of the annulus and, therefore, only this portion need to be attached to a ring to correct the annular dilatation. Annuloplasty device 154 of Fig. 5A has restraining structure 156 which includes curved cross-restraint 158 situated generally along a major axis of ring 152 and extending between junctures 155a, b of ring 152, and transverse restraints 160, extending between and affixed to cross-restraint 158 and ring or posterior segment 152. Similar to the configuration of transverse restraints 134 of Fig. 5A, secondary restraints 160 do not intersect each other within the interior of ring 124 and are not quite parallel to each other. Instead, secondary restraints 160 extend somewhat radially from cross-restraint 158 to posterior segment 152. Annuloplasty device 162 of Fig. 6B has restraining structure 164 having a curved primary restraint or cross-restraint 166 and angled secondary restraints 168. Cross-restraint 166 has a diameter that is thicker than those of the secondary restraints 168.

[0066] Annuloplasty device 170 of Fig. 5C has a restraining structure 172 having a straight primary restraint or cross-restraint 174 extending between distal ends 155 of ring 152. Six secondary restraints 176 form a crisscross pattern extending between ring 152 and primary restraint 174. Unlike various previously described embodiments of the annuloplasty device of the present invention, primary restraint 174 has substantially the same thickness or gauge as the secondary restraints 176.

[0067] Fig. 5D illustrates yet another annuloplasty device 178 having restraining structure 180 which includes a plurality of same-diameter restraints 184. A first group of restraints 184 extend generally radially from respective points proximate left distal end 155a of ring 152 to corresponding respective points on the right side of ring 152. A second group of the restraints 184 extend generally radially from respective points

proximate right distal end 155b of ring 152 to corresponding respective points on the left side of ring 152, thereby forming a web-like pattern with the first group of restraints 184. Any suitable number of groups of restraints may be employed with the annuloplasty devices of the present invention.

[0068] Figs. 6A and 6B illustrate other annuloplasty devices 190 and 202, each having a semi-rigid, partial saddle-shaped annuloplasty ring 192, anterior segments 199a, 199b and posterior segment 200. Surgeons who prefer semi-rigid, partial rings also believe that the annuloplasty can be limited to the posterior annulus but feel that annular remodeling, fixing the anteroposterior dimension of the annulus as well as its circumference, is also important and can only be achieved with a non-flexible ring. Device 190 of Fig. 6A further includes restraining structure 194 having primary restraint 196, situated generally along the major axis of ring 192, and secondary restraints 198 extending radially from primary restraint 196 to posterior segment 202 generally along the minor axis of ring 192. Here, primary restraint 196 has a greater diameter than secondary restraints 198. Device 200 of Fig. 6B further includes restraining structure 204 having primary restraint 206 and transverse restraints 208 extending between primary restraint 206 and posterior segment 200 and forming a crisscross pattern. Here, primary restraint 206 has substantially the same diameter as secondary restraints 208.

[0069] While a number of exemplary embodiments have been particularly described, those skilled in the art of cardiac valve surgery will appreciate that an unlimited number of device configurations is within the scope of the present invention. The suitability of a particular device configuration, ring configuration, and restraining structure configuration (if any), and the numerous permutations thereof, will depend on the particularities of the indication(s) being treated and the particular biases of the implanting surgeon. In other words, any suitable ring shape, contouring, size and thickness may be employed with any suitable restraining structure configuration (if any) including, any suitable number, spacing, length, thickness, relative positioning and attachment means of the individual restraint members being employed.

[0070] More particularly, the rings of the present invention may have shapes which are closed or open, including but not limited to D-configurations, circular configurations, C configurations or saddle configurations. The rings may be planar, substantially planar or non-planar, *i.e.*, have contouring in the shape of a saddle. A full range of ring sizes can

be available to accommodate all adult and pediatric dimensions. The range of horizontal diameters could extend from about 16 to about 44 millimeters but may be longer or shorter. For semi-rigid rings the ratio of the horizontal diameter to vertical diameter could extend from approximately 2.5:1 (Fig. 6A-B) to 3:2 (Fig. 3A-D) to as low as 1:1.

[0071] The primary or cross-restraints of the present invention may have straight (*e.g.*, Figs. 4C and 5C), or bowed or curved (*e.g.*, Figs. 2A, 3A, 3B, 5A, 5B, 6A and 6B) configurations. The primary restraints may curve either towards the posterior segment or the anterior segment of the annuloplasty ring. They can be flexible, semi-rigid or rigid. They can be elastic or non-elastic. They can have a string or bar-like structure with a circular cross-section or be flat and ribbon-like. The primary restraints may have thicknesses that are the same as, greater than or less than the ring itself although generally they would with a diameter ranging from about 0.2 to about 5 millimeters depending on the configuration.

[0072] The secondary or transverse restraints may have the same lengths (*e.g.*, Fig. 4D), substantially the same lengths (*e.g.*, Figs. 3A, 5A-C, 6A and 6B) or varying lengths (*e.g.*, Figs. 2A, 3A, 3B and 3D, 4A, 4C and 5D). Transverse restraints may be parallel (*e.g.*, Figs. 3D), angled (*e.g.*, Figs. 2A, 4A, 4C, 5A, 5B and 6A) to each other or non-parallel forming zigzag (Figs. 3A and 4B), crisscross (*e.g.*, Figs. 3B, 3C, 4C, 5C, 6B and 8), star-like (*e.g.*, Fig. 4D), web-like (*e.g.*, Fig. 5D) or radial patterns (*e.g.*, Figs. 4A, 5A and 6A) or the like. The thicknesses of the restraints may be identical to each other (*e.g.*, Figs. 3C, 3D, 4A, 4B, 5C, 5D and 6B) or vary from restraint to restraint, *e.g.*, the primary restraint (*e.g.*, cross-restraint and annular restraint) may be thicker than the secondary or transverse restraints (*e.g.*, Figs. 2A, 3B, 3D, 4A, 4B, 5A, 5B and 6A) or visa-versa. They can be flexible, semi-rigid or rigid. They can be elastic or non-elastic. They can have a string or bar-like structure with a circular cross-section or be flat and ribbon-like. The primary restraints may have thicknesses that are the same as, greater than or less than the ring itself although generally they would with a diameter ranging from about 0.2 to about 5 millimeters depending on the configuration.

[0073] As mentioned above, the positioning of the secondary or transverse restraints with respect to the primary cross-restraint and/or the ring of the annuloplasty devices of the present invention may vary and include an indefinite number of particular configurations. The transverse restraints may be parallel with each other or non-parallel,

forming an angle at the point of intersection or attachment of a transverse restraint with the ring and/or with a cross-restraint. Generally, these angles range from about 45° to about 90°, typically from about 60° to about 90°, and more typically from about 80° to about 90°. The secondary or transverse restraints may have the same or varying lengths depending on the respective locations of corresponding points of attachment to the ring and/or cross-restraint. Also, the distances between adjacent transverse restraints may be equally spaced or may vary from one to the next. Any suitable number of transverse restraints may be employed with the rings of the present invention. Typically, 3 to 15 transverse restraints are used, and more typically 6 to 10 are employed; however, only 1 or more than 15 may be employed.

MATERIALS

[0074] The rings of the present invention consist of an inner frame made of metal, such as stainless steel or titanium, or of a flexible material, such as silicone rubber or Dacron cordage. The inner frame is covered with a biocompatible fabric or cloth such as Dacron, polytetrafluorethylene (PTFE), which must allow a needle to penetrate, hold a suture and promotes tissue ingrowths and healing. The rings may be rigid, semi-rigid or flexible. The cross- or transverse restraints may be made of any of the material with which the outer ring can be made or any biocompatible, non-absorbable suture-like material such as PTFE, polypropylene, polyester and nickel-titanium. The restraints may be rigid, semi-rigid or flexible, and may be elastic or inelastic, and may be cord-like or ribbon-like. Additionally, they may be contiguous with (*i.e.*, extensions of) the covering of the ring or may be attached to it in a secure fashion such as a knot, loop or other connection.

METHODS

[0075] The various methods of the present invention for using the subject devices and for repairing cardiac valves will now be discussed in detail. The following subject methods will primarily be described in the context of repairing a mitral valve in a conventional fashion through a full sternotomy. However, those skilled in the art will understand the necessary modifications to the procedure in order to access and repair the other cardiac valves through standard or less invasive approaches.

[0076] After prepping and placing the patient under anesthesia, an intra-operative transesophageal echocardiogram (TEE) is usually performed to assess the heart and valves. A careful assessment of the location and type of dysfunction on the TEE can be critical in planning the appropriate surgical procedure and annuloplasty device. It can accurately predict the need for adjunctive procedures to the leaflets and subvalvular apparatus in addition to the annuloplasty device which can in turn determine whether a minimally invasive approach is advisable. A surgical incision is then made in the patient's chest. The conventional, and still most common, approach would be through a full median sternotomy. Other less invasive approaches include a partial sternotomy and a right (or less frequently left) full, partial or "mini" thoracotomy. Mitral valve repair procedures using the present invention would likely be more amenable to these less invasive approaches as the need for complex adjunctive procedures beyond annuloplasty device insertion will be eliminated or minimized.

[0077] Cardiopulmonary bypass is then established, typically by inserting cannulae into the superior and inferior vena cavae for venous drainage and into the ascending aorta for arterial perfusion. The cannulae are connected to a heart-lung machine which oxygenates the venous blood and pumps it into the arterial circulation. Additional catheters are usually inserted to deliver "cardioplegia" solution, which is infused into the heart after isolating it from the circulation with a clamp on the aorta and stop it from beating. Numerous modifications of this basic technique are possible, commonly used, especially in minimally invasive procedures, and are understood by those skilled in the art of cardiac surgery. Once cardiopulmonary bypass and cardiac standstill have been achieved, the mitral valve is exposed by entering the left atrium and retracting the atrial tissue away using sutures or retraction devices. The atriotomy (entry incision) is usually made in the right side of the left atrium, anterior to the right pulmonary veins, although other approaches are occasionally used, especially in minimally invasive procedures.

[0078] Once good exposure of the mitral valve has been achieved, a careful valve analysis or "interrogation" is performed. Each segment of each leaflet is carefully assessed using special forceps and hooks to determine its pliability, integrity and motion. Based on this assessment, the surgeon determines whether the valve can be repaired or must be replaced. A successful valve repair is considered very likely as long as the leaflets have an adequate amount of pliable (non-calcified) tissue. The leaflet motion is

then classified according to Carpentier's classification as Type I valve dysfunction (normal), Type II valve dysfunction (leaflet prolapse) or Type III valve dysfunction (restricted leaflet motion) and, based on this classification, the necessary steps of the repair are determined. In patients with Type I or IIIB valve dysfunction, the repair can nearly always be achieved with insertion of an appropriately sized (true-sized for Type I valve dysfunction and down-sized for Type IIIB valve dysfunction) remodeling annuloplasty ring alone. With conventional annuloplasty rings, however, patients with Type II or IIIA valve dysfunction usually require sometimes extensive, adjunctive procedures such as multiple leaflet resections and chordal transfers in Type II valve dysfunction or leaflet extension and chordal resection in Type IIIB valve dysfunction.

[0079] With the annuloplasty devices in the present invention, many if not most patients will not require any adjunctive procedures since the net-like restraining structure of the device will correct any prolapse by preventing the dysfunctional segment from rising above the plan of the annulus into the left atrium. In selected patients the surgeon may choose to perform limited adjunctive procedures prior to implanting the annuloplasty device; however the number and complexity of these procedures are will be significantly less than in conventional mitral valve repair. For example, if a valve suffering from Type II dysfunction is noted to have a large redundant prolapsing segment of the posterior leaflet, the surgeon may chose to perform a limited resection of the redundant posterior leaflet prior to implanting the device to prevent this excess tissue from obstructing flow within the left ventricle. With devices of the present invention, however, the surgeon can ignore residual prolapse of either leaflet and would not need to perform any complex adjunctive procedure such as a sliding valvuloplasty of the posterior leaflet or any procedure on the anterior leaflet. In a patient with Type IIIA disease (restricted leaflet motion usually due to fibrosis from rheumatic heart disease), the surgeon may chose to resect multiple restricted chordae to either leaflet to improve their mobility without having to worry about correcting any resulting leaflet prolapse.

[0080] The implantation of the annuloplasty devices of the present invention is very similar to that of conventional annuloplasty rings. Any implantation technique currently utilized for annuloplasty ring implantation can be applied to the current device including, but not limited to, interrupted mattress sutures, a continuous running suture, interrupted simple (non-mattress) sutures, specialized clips or staples. The most common method

uses a plurality (typically 6-15) of non-pledgeted horizontal mattress sutures made from a braided, non-absorbable material such as polyester. Successive suture bites are taken deep into the fibrous substance of the annulus in a tangential direction around its circumference. Complete rings require sutures extending around the complete circumference of the annulus. Partial rings, on the other hand, typically terminate just inside each commissure (a dimple known as the “trigone”) and thus do not require placement of sutures along the anterior annulus. The commissural marks on the ring allow the sutures to be properly aligned and ring to be properly oriented within the annulus. Typically all of sutures are placed in the annulus and then through the fabric of the annuloplasty ring before being tied and cut. Alternatively the sutures can be placed into the ring after each bite, a technique that can facilitate minimally invasive implantation. It is not necessary to suture any of the restraining members, either the primary or secondary restraints, to the valve.

[0081] Once the sutures are tied and cut, the repaired valve is tested to confirm a good line of coaptation without residual regurgitation. This is typically performed by injecting saline into the left ventricle until sufficient pressure develops to close the leaflets. Once the valve repair is complete the atriotomy incisions are closed, the entrapped air is removed from the heart, the cross clamp is removed and the heart is reperfused causing it to start beating again. Soon there after the patient is gradually weaned off the support of the heart lung machine. The repaired valve is assessed using the transesophageal echocardiogram. If the repair is satisfactory, the cannulae are removed and the incisions are closed in a fashion consistent with other cardiac surgical procedures.

KITS

[0082] Also provided by the subject invention are kits for use in practicing the subject methods. The kits of the subject invention include at least one subject annuloplasty device of the present invention. Certain kits may include several subject annuloplasty devices having different ring sizes, shapes and/or restraining structure configurations. Additionally, the kits many include certain accessories such as an annulus sizer, a ring holder, suturing devices and/or sutures. Finally, the kits may include instructions for using the subject devices in the repair of cardiac valves, particularly the mitral and

tricuspid valves. The instructions for use may include, for example, language instructing or suggesting to the user the most appropriate ring shape and/or type of restraining configuration for treating a particular indication. These instructions may be present on one or more of the packaging, a label insert, or containers present in the kits, and the like.

[0083] It is evident from the above description that the features of the subject annuloplasty devices and methods overcome many of the disadvantages of prior art annuloplasty rings and valve repair procedures including, but not limited to, minimizing the number or adjunctive procedures and instruments necessary to completely repair a cardiac valve, simplifying the repair procedure allowing more surgeons to offer this procedure to their patients and facilitating minimally invasive approaches to valve repair. As such, the subject invention represents a significant contribution to the field of cardiac valve repair.

[0084] While the present invention has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt to a particular indication, material, and composition of matter, process, process step or steps, while achieving the objectives, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.